IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

RITE AID CORPORATION AND RITE AID HDQTRS. CORP., **Plaintiffs,** **v.** **ALLERGAN, INC.,** **Defendant.**	Case No.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. ("Plaintiffs" or "Rite Aid") bring this civil antitrust action against Defendant Allergan, Inc. ("Allergan") and allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking permanent injunctive relief, treble damages, and other relief to redress Allergan's unlawful scheme to maintain its monopoly in the United States market for ophthalmic cyclosporine emulsion, which Allergan markets under the brand name Restasis. Allergan unlawfully maintained its monopoly through a scheme that included, *inter alia*, making material misrepresentations and omissions to the United States Patent and Trademark Office ("PTO") that allowed it to obtain patents to which it was not entitled; improperly listing those patents in the FDA's Orange Book; filing a series of sham citizen petitions with the FDA designed to delay generic competition; suing generic competitors for alleged infringement of the invalid and unenforceable patents; and transferring ownership of the invalid patents to a sovereign Native American tribe in order to avoid judicial scrutiny of the patents.

2. Allergan made about $3.3 billion selling Restasis in the United States for eleven and a half years, during which time the drug was protected by U.S. Patent No. 5,474,979 ("the '979 Patent") and was the only ophthalmic cyclosporine emulsion sold in the U.S. Not satisfied with the $3.3 billion that it earned during this time, Allergan devised and carried out a multifaceted and anticompetitive scheme to maintain that monopoly and prevent would-be generic competitors from competing with Restasis by selling AB-rated generic versions of the drug. That scheme included each of the following elements:

3. ***Fraud on the PTO.*** After the PTO rejected Allergan's efforts to obtain new and additional patents covering Restasis, Allergan resorted to falsely claiming that clinical data on

the drug showed unexpected effectiveness and surprising test results. The patent examiner, relying on these false claims, allowed additional patents to issue (the "follow-on patents") that would not have issued in the absence of Allergan's misrepresentations. Those patents were invalid as obvious in light of the prior art and unenforceable due to Allergan's fraud.

4. ***Wrongful Orange Book listing.*** After obtaining the follow-on patents, Allergan improperly listed them in the Orange Book, thereby forcing would-be generic competitors to file so-called "paragraph IV" certifications challenging the patents and giving Allergan the opportunity to sue them under the Hatch-Waxman Act. The FDA lists all patents submitted for listing in the Orange Book. Its acceptance of the patents for listing is a ministerial act, and it does not review the patents for validity, enforceability, or infringement. Because the follow-on patents were invalid and unenforceable, Allergan should not have submitted them for listing.

5. ***Wrongful FDA petitions.*** After improperly obtaining and listing the follow-on patents in the Orange Book, Allergan submitted a series of petitions to the FDA asking the FDA not to approve generic versions of Restasis until generic competitors invested time and money satisfying unnecessary conditions that are not typically imposed on generic manufacturers seeking approval to market AB-rated generic versions of already approved branded drugs. The conditions were particularly unnecessary for a topical treatment with no significant adverse event history. No reasonable pharmaceutical company in Allergan's position would have expected the FDA to grant the relief Allergan sought, and in fact, the FDA denied all of the substantive relief sought by Allergan.

6. ***Wrongful patent litigation.*** Upon receiving paragraph IV certifications from would-be generic competitors Actavis (formerly known as Watson) in 2015 and Apotex, Akorn, Teva and Mylan in 2015, Allergan sued each competitor for patent infringement. It did so knowing that the data the PTO had relied on in issuing the patents was neither new nor

unexpected. Each generic defendant alleged that the follow-on patents were invalid. No reasonable litigant in Allergan's position would realistically have expected to win any of those cases on the merits, and Allergan did not in fact expect to win on the merits. Allergan filed the lawsuits simply to trigger the automatic thirty-month stay of FDA approval and delay the entry of its generic competitors.

7. ***Conspiracy in restraint of trade.*** In December 2016, the Patent and Trademark Appeal Board ("PTAB") held that there was a reasonable likelihood that the follow-on patents would be invalidated as a result of *inter partes* review. Faced with this prospect, Allergan entered into an unlawful contract with the Saint Regis Mohawk Tribe (the "Tribe") to transfer ownership of the follow-on patents to the Tribe and then petitioned the PTAB to dismiss its review for lack of subject-matter jurisdiction based on the Tribe's sovereign immunity. This unlawful agreement was another attempt to maintain its monopoly in the relevant market by insulating the invalid follow-on patents from review. Allergan's only reason for transferring ownership to the Tribe was to avoid a review of the patents that Allergan knew it was certain to lose.

8. As a result of Allergan's scheme, Allergan maintained its monopoly and prevented AB-rated generic competition to Restasis. But for these actions, generic Restasis would have been available in the United States on or shortly after May 17, 2014, and Plaintiffs (as well as other purchasers) would have purchased less expensive generic Restasis rather than branded Restasis for the vast majority of their ophthalmic cyclosporine emulsion requirements. As a result of Allergan's scheme, there is still no generic Restasis available today.

II. PARTIES

9. Plaintiffs Rite Aid Corporation and Rite Aid Hdqtrs. Corp. (collectively "Rite Aid") are corporations organized and existing under the laws of the State of Delaware with a

principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public. Rite Aid brings this action on its own behalf and as the assignee of McKesson Corporation, which during the relevant period purchased Restasis directly from Allergan for resale to Rite Aid and which has assigned its claims arising out of those purchases to Rite Aid.

10. Defendant Allergan is a Delaware corporation having its principal place of business at 2525 Dupont Drive, Irvine California 92612. Allergan is the holder of approved New Drug Application No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the brand name Restasis. Allergan was also the applicant or assignee for and holder of each of the follow-on patents that Allergan has claimed cover Restasis: No. 8,629,111 (issued Jan. 14, 2014); No. 8,633,162 (issued Jan. 21, 2014); No. 8,642,556 (issued Feb. 4, 2014); No. 8,648,048 (issued Feb. 11, 2014); No. 8,685,930 (issued April 1, 2014); and No. 9,248,191 (issued Feb. 2, 2016).

11. All of the actions attributed to Allergan in this Complaint were carried out by Allergan's officers, agents, employees or other representatives while actively engaged in the management of Allergan's affairs and within the course and scope of their agency or employment by Allergan, and/or with actual, apparent or ostensible authority.

III. JURISDICTION AND VENUE

12. This action arises under section 2 of the Sherman Act, 15 U.S.C. § 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26. It seeks permanent injunctive relief, treble damages, costs of suit and reasonable attorney's fees for the injuries sustained by Plaintiffs as a result of Allergan's unlawful foreclosure of generic cyclosporine sales in the United States. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a).

13. The Court has personal jurisdiction over Defendant and venue is proper in this district pursuant to 15 U.S.C. §§ 15(a) and 22 and 28 U.S.C. §§ 1391 and 1407 because during the relevant period, Allergan resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged unlawful activity was carried out in this district.

IV. BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

14. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person both pays for and chooses the product, price plays an appropriate role in the person's choice of products and, consequently, manufacturers have an appropriate incentive to lower the prices of their products.

15. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Restasis, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

16. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand

pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

17. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand -- the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

18. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

19. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must submit for listing in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer must also submit any such patent

issued after the FDA approves the NDA within thirty days of its issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

20. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability in including submitted patents in the Orange Book, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Amendments

21. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterparts.

22. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one

another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

23. Congress enacted the Hatch-Waxman Amendments to expedite the entry of low-cost generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

24. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total prescription drug revenue had soared to $300 billion.

D. Paragraph IV Certifications

25. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

26. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

27. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

28. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition -- as opposed to enforcing a valid patent that is actually infringed by the generic -- is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

29. Brand-name pharmaceutical manufacturers can also game the system by filing citizen petitions. Under FDA regulations, any person or entity can file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. The person or entity submitting such a petition is required to include all information and views on which the petitioner relies, as well as information and data known to the petitioner, which is unfavorable to the petition.

30. Although federal regulations provide a 180-day period for the FDA to respond to citizen petitions, the FDA often takes longer in practice. Historically, the FDA's practice has been to refrain from approving an ANDA that is the subject of a pending citizen petition until it rules on the petition. Branded manufacturers have been known to file baseless citizen petitions solely to delay ANDA approval and thereby preserve their monopolies while the petition is pending. The cost of filing a sham citizen petition is trivial compared to the value to the manufacturer of delaying AB-rated generic competition.

31. The tactic of filing sham citizen petitions became such a problem that in 2007 Congress stepped in and revised the FDCA to provide that the FDA could not delay approval of

a pending ANDA because of a petition unless it determines that "a delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1). The FDA continues to express concerns about the abuse of the citizen petition process for anticompetitive purposes. In its 2016 report to Congress, like the reports from prior years, the FDA stated that it was "concerned that section 505(q) may not be discouraging the submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products."[1]

E. Benefits of Generic Drugs

32. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains such as Plaintiffs, a generic typically achieves a 90% substitution rate within 90 days. As a result, competition from generic drugs is viewed by brand name drug companies such as Allergan as a grave threat to their bottom lines.

[1] FDA., *Ninth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2016* 6 (Jan. 8, 2018), *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM605276.pdf.

33. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally substitute the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

34. There is an incentive to choose the less expensive generic equivalent at every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices that result from generic competition.

35. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market including by using tactics such as those at issue here.

V. OPERATIVE FACTS

A. FDA Approval of Restasis

36. Cyclosporine treats dry eye disease, also known as keratoconjunctivitis sicca ("KCS"), a painful and irritating condition involving abnormalities and deficiencies in the tear film of the eye. More severe cases of dry eye can involve or precipitate inflammation with serious potential damage to the ocular surface.

37. Allergan manufactures and sells the prescription drug cyclosporine under the brand name Restasis, an emulsion consisting of various components, including the active ingredient cyclosporin A,[2] an immunosuppressant, which is dissolved in castor oil, a fatty acid glyceride. Restasis is one of the most widely prescribed drugs in the world. Last year, sales of Restasis in the United States alone were nearly $1.5 billion.

38. In 1993, Allergan licensed from Sandoz, Inc., the technology of treating aqueous-deficient dry eye with cyclosporine. That technology was the subject of U.S. Patent No. 4,839,342 to Kaswan ("the '342 patent" or "the Kaswan patent"). The Kaswan patent claimed methods for enhancing or restoring lacrimal gland tearing comprising topically administering cyclosporine to the eye in a pharmaceutically acceptable vehicle. The Kaswan patent also recited the use of castor oil, among other compounds, as a pharmaceutically acceptable vehicle for delivering cyclosporine to the eye.

39. Because cyclosporine is highly insoluble in water, Allergan had to develop an oil-in-water emulsion castor oil (a hydrophobic vehicle that would dissolve the cyclosporine), together with an emulsifier and an emulsion stabilizer in water. Allergan disclosed this work in two patents, the first of which was U.S. Patent No. 5,474,979 ("the '979 patent" or "the Ding I patent"), which issued in 1995. The Ding I patent contained four examples, the first two of which contained multiple formulations drawn from the disclosed and claimed ranges of components. This range included 0.05% to 0.40% cyclosporine and 0.625% to 5.00% castor oil. The Ding I patent stated that the preferred weight ratio of cyclosporine to castor oil was below 0.16 (which is the maximum solubility level of cyclosporine in castor oil), and that the more

[2] Cyclosporin A is sometimes spelled "cyclosporine" to distinguish it from other cyclosporins, such as cyclosporins B, C, and D. See U.S. Pat. No. 4,839,342, col. 3, ll. 7-11.

preferred weight ratio of cyclosporine to castor oil was between 0.02 and 0.12. The formulation of Restasis falls within the range of values disclosed and claimed in the Ding I patent.

40. The second patent, U.S. Patent No. 5,981,607 ("the '607 patent" or "the Ding II patent"), is entitled "Emulsion Eye Drop for Alleviation of Dry Eye Related Symptoms in Dry Eye Patients and/or Contact Lens Wearers." The Ding II patent disclosed and claimed a method of alleviating dry eye related symptoms by topically applying to ocular tissue an emulsion of a higher fatty acid glyceride, polysorbate 80, and an emulsion-stabilizing amount of Pemulen in water, all without cyclosporine.

41. Allergan conducted clinical trials of various combinations of cyclosporine and castor oil. In the first clinical trial (the "Phase 2" study), Allergan tested many of the combinations listed in Ding I, attempting to ascertain the appropriate dosage (e.g., 0.1% cyclosporine with 1.25% castor oil; 0.2% cyclosporine with 2.5% castor oil). The results were published in the article Dara Stevenson et al., *Efficacy and Safety of Cyclosporine A Ophthalmic Emulsion in the Treatment of Moderate-to-severe Dry Eye Disease, A Dose-Ranging, Randomized Trial*, 107 OPHTHALMOLOGY 967 (May 2000). The study concluded that all tested concentrations significantly improved the ocular signs and symptoms of moderate-to-severe dry eye disease, and mitigated dry eye disease's effects on vision-related functioning. All tested concentrations were safe and effective in increasing tearing in certain patient groups.

42. Notably, Stevenson concluded that there was no clear dose-response relationship -- efficacy did not increase with increases in dosage amounts. However, the 0.1% cyclosporine formulation "produced the most consistent improvement in objective and subjective endpoints (such as superficial punctate keratitis and rose bengal staining)," while the 0.05% cyclosporine formulation "produced the most consistent improvements in patient symptoms (such as sandy/gritty feeling and ocular dryness)." *Id.* at 974. Therefore, Stevenson's study

suggested that "subsequent clinical studies should focus on the cyclosporine 0.05% and 0.1% formulations." *Id.*

43. Phase 3 trials did that, and the results were published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 OPHTHALMOLOGY 631 (April 2000). Phase 3 confirmed the results of Phase 2. It found that the 0.05% cyclosporine resulted in significantly greater improvements than castor oil alone, though castor oil alone also produced significant improvements over the patient's baseline, suggesting that it was a contributing factor to the formulations' success.

44. Statistically, there was no significant difference between the 0.05% cyclosporine formulation and the 0.1% formulation in either Phase 2 or 3.

45. Following the Phase 3 study, Allergan filed a New Drug Application ("NDA") with the FDA seeking authorization to market the 0.05% cyclosporine product that was tested in the Phase 3 trials. The proposed commercial product, which is Restasis, contained all of the components of the Phase 3 0.05% cyclosporine formulation, including 1.25% castor oil. The FDA approved the application in December 2002, authorizing the sale of Restasis for the following indication: "Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen

in patients currently taking topical anti-inflammatory drugs or using punctal plugs."[3] Since its launch in 2003, Restasis has been a highly successful product for Allergan.[4]

B. Allergan's Prosecution of Serial Flawed Patent Applications to Extend the Restasis Monopoly

1. The PTO's repeated rejection of Allergan's serial efforts to obtain additional patents for "new" combinations of castor oil and cyclosporine that were obvious in light of prior art.

46. For over a decade following the FDA's approval of Allergan's Restasis NDA, Allergan filed various patent applications focusing on patenting combinations of castor oil and cyclosporine, notwithstanding the earlier published work that already claimed a broad range of combinations, with no statistically different outcomes based on the particular combination. One of the series of applications that Allergan filed was U.S. Patent Application No. 10/927,857 ("the '857 application") on August 27, 2004. The '857 application and dependent claims were again based on combinations of cyclosporine and castor oil within the range covered by Ding I. Allergan withdrew a number of the claims of the '857 application, and unsurprisingly, the PTO examiner rejected the remaining claims based in part on obviousness in light of the Ding I patent.

47. Allergan amended the '857 application in 2007 to include a claim to an emulsion comprising water, 1.25% castor oil, and 0.05% cyclosporine, which is the percentage of those

---

[3] The FDA's Medical Review for Restasis does not support Allergan's claim that the results of the Phase 3 studies were unexpected. The FDA did not conduct a pair-wise comparison between the 0.05% cyclosporine formulation and the 0.1% formulation, and it drew no statistical conclusions from the relative performance of the two cyclosporine formulations.

[4] In 2003, particularly in light of the results published in Kenneth Sall et al., *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 OPHTHALMOLOGY 631 (April 2000), Restasis's success was not surprising. At the time, the prior art taught towards, not away from, using a 0.05% cyclosporine/1.25% castor oil emulsion as a potentially effective treatment for dry eye.

components in Restasis, and as would be expected, the PTO examiner again rejected the application. Allergan appealed, and in 2007, while the appeal was pending, Allergan filed a continuation of the '857 application, U.S. Patent Application No. 11/897,177 ("the '177 application"). The '177 application was similar to the '857 application, but added claims regarding new conditions that the method was asserted to treat, including corneal graft rejection.

2. Allergan's 2009 concession that all "new" cyclosporine/castor oil combination claims were obvious in light of Ding I.

48. In June 2009, Allergan contradicted its earlier patentability claims and conceded, with respect to both the '857 and '177 applications, that the various composition claims were obvious in light of Ding I. Allergan explained, in writing, that it "concede[d] that it would have been obvious to modify examples 1A-1E of the Ding reference to arrive at Composition II of the present application. The differences are insignificant." Allergan, in its own words, "concede[d] that in making this selection (0.05% cyclosporine and 1.25% castor oil) there would have been a reasonable expectation of success; the differences between Examples 1A-1E and [the Restasis formulation] are too small to believe otherwise." According to Allergan, the composition claims advanced by the '857 and '177 applications were "squarely within the teaching of the Ding reference, and the Office should disregard any statements by the applicants suggesting otherwise, whether in [either the '857 or '177 applications]." Allergan withdrew its then-pending appeal.

49. After canceling the previous claims on the '857 application, Allergan tried once more to add to it a new claim regarding another composition of cyclosporine and castor oil. As with all the other composition claims, the PTO examiner rejected the new composition claim as obvious in light of Ding I (and for non-statutory double patenting over Ding I). By April 2011, a notice of abandonment was entered on the '857 application. The '177 application ultimately

issued as U.S. Patent No. 8,618,064, but was narrowly limited to only the additional use for the treatment of corneal graft rejection.

3. Allergan's series of new continuation applications in August 2013 deriving from the '177 application.

50. Having repeatedly failed to convince the PTO to grant patent protection over various "new" composition claims, and with the May 2014 expiration of Ding I on the immediate horizon, Allergan in August 2013 filed six additional continuation applications deriving, directly or indirectly, from the '177 application. The six additional applications were identical except for minor variations. In each, the revised specification added four sentences that further described the role of cyclosporine as an immunosuppressant and the conditions that can be treated with cyclosporine. As a federal court invalidating the patents that subsequently issued from these applications later found, "[t]he new applications were intended to protect the Restasis composition and the method of using that composition in treating dry eye and KCS after the expiration of the Ding I patent in 2014." *Allergan, Inc. v. Teva Pharms USA, Inc.*, No. 2:15-cv-01455, ECF No. 523 at 20 (E.D. Tex. Oct. 16, 2017) ("Invalidation Decision").

51. In initiating these 2013 applications, Allergan tried to retract its prior concession that various cyclosporine-castor oil combinations were obvious in light of Ding I. It claimed to have new data that supported patentability by establishing "unexpected" results that the claimed Restasis formulation was particularly effective. The PTO again rejected the claims presented by the 2013 applications as obvious in light of Ding I.

52. Responding to that rejection, Allergan submitted declarations executed in October 2013 from two of its scientists, which according to Allergan, demonstrated that the Restasis formulation outperformed other combinations to a "surprising" extent not anticipated by Ding I

and other prior art. Specifically, Allergan represented to the PTO examiner that Dr. Schiffman's declaration demonstrated surprising test results:

> [T]he claimed formulation [of 0.05% cyclosporin and 1.25% castor oil] demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compared to the relative efficacy for the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation discussed in Example 1E of Ding, tested in Phase 2 trials. The data presented herewith represents the subpopulation of Phase 2 patients with the same reductions in tear production (x 5mm/5 min) as those enrolled in the Phase 3 studies. . . . Exhibits E and F also illustrate that the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the 0.05% by weight cyclosporin A/0.625% by weight castor oil formulation tested in Phase 2 and disclosed in Ding (Ding 1E). This was clearly a very surprising and unexpected result.

53. On the basis of this representation about Dr. Schiffman's discovery and the declaration itself, the PTO examiner reversed course. The examiner stated that the Schiffman declaration "is deemed sufficient to overcome the rejection ... based on [Ding I] ... because ... Examiner is persuaded that, unexpectedly, the claimed formulation ... demonstrated an 8-fold in increase in relative efficacy . . . ." The Examiner allowed all six applications, which issued in early 2014 as U.S. Patent Nos. 8,629,111 ("the '111 patent"), 8,633,162 ("the '162 patent"), 8,642,556 ("the '556 patent"), 8,648,048 ("the '048 patent"), 8,685,930 ("the '930 patent"), and in 2016 as U.S. Patent No. 9,248,191 ("the '191 patent"). These are the follow-on patents at issue here.

4. Allergan's 2013 data was neither new nor unexpected.

54. The statements and data reflected in Dr. Schiffman's declaration were not new. Dr. Schiffman's declaration consisted of statements plagiarized from an article published in a well-known medical journal thirteen years earlier, Sall et al., *Two Multicenter, Randomized*

Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease, 107 OPHTHALMOLOGY 631 (April 2000) ("Sall Article"). Moreover, the plagiarized article relied on Allergan's very own Restasis Phase 3 clinical trial data, which Allergan itself had recorded in the 1990s. In fact, this was the very publication that publicized Allergan's Phase 3 clinical results.

55. Not only was the "new" 2013 data not new, it did not demonstrate unexpected results. As the federal court which invalidated the follow-on patents recently found:

> [Allergan's] presentation to the PTO substantially overstated the difference between the clinical results obtained with the Ding formulations and the clinical results obtained with the Restasis formulation. The actual clinical results, interpreted properly, show no significant difference in efficacy between the Restasis formulation and the 0.1% formulation that was Example 1D of the Ding I patent.

Invalidation Decision at 133.

56. In submitting the 2013 continuing applications, Allergan sought new patent protection of substantially the same claims the PTO examiners had rejected on numerous prior occasions. These "new" claims were also negated by Allergan's concession in 2009 of obviousness in light of prior art. The PTO granted these claims only in reliance on Allergan's Schiffman Declaration and Allergan's characterization of that Declaration as establishing "new" data and surprising results not contemplated by the prior art.

57. Allergan made these representations and characterizations with the intent to deceive the PTO, and such representations and characterizations were material and fraudulently induced the PTO to grant the follow-on patents. As a federal court later found:

> To the extent that Allergan relies on Dr. Schiffman's presentation to the PTO . . . and the fact that the examiner concluded that unexpected results had been shown . . . the Court finds that the presentation made to the examiner in 2013, including Dr. Schiffman's declaration and the accompanying exhibits, ***painted a***

> ***false picture*** of the comparative results of the Phase 2 and Phase 3 trials. In addition, that presentation ***created the misleading perception*** that the evidence that Dr. Schiffman relied on to show unexpected results was not known at the time of the invention. Accordingly, the Court regards the examiner's finding of unexpected results to be entitled to no weight, based as it was on evidence that ***did not accurately depict*** the comparative results of the two Allergan studies and that was, in any event, disclosed in the prior art.

Id. at 82-83 (emphasis added).

58. Had Allergan made clear to the PTO examiner that the Schiffman Declaration statements and data were lifted from prior art known to Allergan for over 10 years, as its duty of disclosure, candor and good faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every other prior application: the claims presented were all obvious in light of the prior art.

C. Allergan's Wrongful Listing of its Invalid Follow-on Patents in the Orange Book.

59. The first follow-on patent to issue was the '111 patent on January 14, 2014. Allergan immediately listed it in the Orange Book. This listing required any ANDA filer seeking to market generic Restasis to file a certification as to that "new" patent.

60. The FDA has acknowledged, however, that shortly before the issuance of the '111 patent, the Agency had received at least one ANDA for generic Restasis. Up until the listing of the follow-on patents, ANDAs for generic Restatis could be filed with paragraph ii and/or iii certifications, which meant that the generic would not be marketed until after expiration of Ding I in May 2014. Absent Allergan's procurement and listing of the follow-on patents, any Restasis ANDAs with paragraph ii and/or iii certifications would have been approved on or shortly after May 17, 2014, and generic competition to Restasis would have created immediate benefits to Plaintiffs in the form of lower prices.

61. Instead, once the follow-on patents issued, all prior ANDA filers had to amend their ANDAs to include paragraph IV certifications with respect to the '111 patent (and eventually the other follow-on patents). Worse, the confusion Allergan created through its eleventh-hour patent applications and Orange Book listings meant that the order in which the FDA received any prior ANDA certifications likely was different from the order in which the agency received the paragraph IV certifications with respect to the follow-on patents, creating various first-filer-status uncertainties.

62. The wrongful Orange Book listings had another immediate impact: by requiring all ANDA applicants to file paragraph IV certifications with respect to the follow-on patents, they created a mechanism for Allergan to sue for infringement and trigger the automatic stay of any FDA approval of such ANDA for up to 30 months. In contrast, ANDAs with paragraph ii or paragraph iii certifications are not subject to that automatic 30-month stay of FDA approval.

63. Allergan knew when it listed the follow-on patents in the Orange Book that such patents were invalid. It nevertheless understood that those invalid patents could be used to delay generic Restasis competition beyond May 2014 and would create confusion that would further chill the FDA's ANDA approval process.

D. Allergan's Sham Patent Infringement Suits.

64. In response to Allergan's Orange Book listings, and exactly as Allergan had planned, generic competitors provided paragraph IV certifications with respect to the follow-on patents. Generic manufactures Apotex, Akorn, Mylan, and Teva all submitted paragraph IV certifications within weeks of each other starting in July 2015, asserting that the follow-on patents were either invalid or non-infringed. Because the patents were procured by fraud and otherwise invalid as obvious in light of Ding I and other prior art, Allergan had no legitimate

basis to enforce them. Yet Allergan responded to each of the above paragraph IV certifications from potential generic competitors by filing multiple patent infringement actions, beginning on August 24, 2015.

65. These infringement suits triggered the automatic 30-month stay of FDA final approval of these ANDAs.

66. These suits were both objectively baseless, because no reasonable litigant would have realistically expected to succeed on the merits, and subjectively baseless, because Allergan's motivation in filing them was merely to delay the commencement of generic competition through the process of litigating rather than the outcome of the litigation.

67. On October 16, 2017, after trial in August, the Texas federal court found the follow-on patents invalid based on obviousness. In a thorough 135-page post-trial Findings of Fact and Conclusions of Law, the court found that Allergan had secured these Patents "by way of a presentation that was more advocacy than science." Invalidation Decision at 133. The court found particularly compelling the 2009 concessions, the fact that Allergan's "unexpected" results were foreseeable based on the early cyclosporine studies, and that in any event, the "new" Restasis formulation claimed by the follow-on patents had statistically the same efficacy as one of the prior art examples in Ding I.

68. The court also dismissed other arguments Allergan made at trial, including assertions that the surprise results arose from a difference between the Phase 2 and 3 studies, and that there were objective, valid reasons for issuing new patents:

> While Allergan has pointed to evidence of objective considerations such as commercial success and long-felt unmet need, the force of that evidence is considerably blunted by the fact that, based on protection from a succession of patents, Allergan was able to foreclose competition in cyclosporin/glyceride emulsion formulations from the early 1990s until 2014. And the issuance of the [follow-on] Restasis patents has barred any direct competition

> for Restasis since then. The evidentiary value of the objective consideration evidence has thus been considerably weakened by the existence of blocking patents during the critical period.[5]

69. Allergan brought these multiple infringement suits without regard to their objective merit. Indeed, Allergan had conceded in 2009 that the claims in the '857 and '177 applications (the basis for what issued as the follow-on patents) were obvious in light of Ding I, and Allergan knew it had obtained the follow-on patents only through its fraudulent misrepresentations to the PTO. Accordingly, there never was any objective merit to any of these infringement suits. The objective merits were irrelevant, however, to Allergan. Allergan filed those suits not to vindicate any legitimate patent infringement issues but to improperly use governmental process and the workings of the Hatch-Waxman act to delay generic Restasis competition.[6] If it filed even the most baseless of patent infringement suits, Allergan knew it would still obtain and immediately benefit from the automatic 30-month stay of FDA final approval of any generic Restasis product. For a $1.5 billion/year franchise, every extra month Allergan could postpone competition from generic Restasis added another $125 million to its revenues.

---

[5] *Id.* at 134-35. The Court noted that Allergan had success and met a need not because it was at the forefront of innovation in a competitive setting, but because it had enjoyed a long period of patent protection, which ensured that it was the only party able to invent and exploit a cyclosporine/castor oil product.

[6] Indeed, Allergan's subjective intent in filing these suits is evident from the complaint it filed. In its prayer for relief, Allergan demanded that the Texas federal court order, notwithstanding its lack of authority to do so, that "the effective date of any FDA approval" of any Restasis ANDA be "a date which is not earlier than the latest expiration date . . . including any extensions or periods of exclusivity" of the follow-on patents. See ECF No. 96 at 127, 129, 131, 132.

E. Allergan's Abuse of the FDA Citizen Petition Process to Delay Generic Entry

70. Another prong of Allergan's multifaceted scheme was to delay the FDA's approval of any Restasis ANDA by hijacking the agency's citizen petition process.

71. Allergan's citizen petitions related to FDA's June 2013 non-binding, draft guidance giving Restasis ANDA applicants two options to demonstrate the bioequivalence necessary to secure FDA ANDA approval. Pursuant to the June 2013 draft guidance, Restasis ANDA applicants could establish the bioequivalence of generic Restasis to its branded counterpart by: (1) *in vivo* testing (i.e., testing performed on live humans, often referred to as "clinical endpoint studies"); or (2) *in vitro* testing (i.e., testing in a test tube). Generic drug makers typically use *in vitro* testing in their ANDAs to demonstrate bioequivalence with a branded drug, because it is cheaper and less time-consuming than *in vivo* clinical trials. Brand-name drug companies generally must undertake *in vivo* testing to support the original NDA, and a primary objective of Hatch-Waxman was to relieve generic applicants of the unnecessary burden of such studies, which the FDA believes "may present economic and logistical challenges for ANDA sponsors."

72. Allergan gave the FDA its views on the draft guidance in a lengthy comment submitted to the agency in August 2013, asserting that the FDA could not approve any Restasis ANDA relying on *in vitro* testing and asking the FDA to "replace the Draft Guidance with a revised guidance document that explains *in vivo* comparative clinical studies are required to demonstrate that a proposed generic product is bioequivalent to" Restasis. Allergan's criticism of the draft guidance was echoed by comments submitted by several doctors who, unbeknownst to the FDA, had in 2013 received payments of up to $70,000 from Allergan for "consulting" on Restasis. The FDA typically publishes its responses to the public comments received in response

to its draft guidance, but is not required (as it is with a citizen petition) to formally respond to individual requests to take (or refrain from taking) action.

73. Despite having already aired its criticism of the FDA's draft guidance during the August 2013 comment period, Allergan nonetheless began inundating the FDA with citizen petitions immediately following its improper listing of the first follow-on patent in the Orange Book in January 2014. While Allergan asserted that its citizen petitions were submitted to tell the FDA that "rushing prematurely to approve a proposed generic drug [not supported by *in vivo* clinical endpoint studies] poses a risk to patient health," Allergan's true goal was to delay the FDA's review of any Restasis ANDAs by saddling the agency with baseless, duplicative citizen petitions relating to the 2013 draft guidance -- a tactic that Allergan told investors exemplified its response to "intense competition from generic drug manufacturers."

74. Allergan submitted its first citizen petition to the FDA on January 15, 2014. That petition was superseded shortly thereafter by another citizen petition filed on February 28, 2014 (the "February 2014 Citizen Petition"), which largely parroted Allergan's public comments to the FDA in August 2013. Among the February 2014 Citizen Petition's six requests -- each of which required a formal, time-consuming response from the FDA within 180 days -- was a request that the FDA "make clear that the only way to demonstrate bioequivalence to Restasis is through comparative clinical endpoint studies [i.e., *in vivo* testing]," and "refus[e] to accept or approve any [Restasis] ANDA if it does not include data from one or more appropriately designed comparative clinical trials to demonstrate bioequivalence." The February 2014 Citizen Petition cited to the public comments submitted by its cadre of paid doctors, ostensibly "draw[ing] from their clinical experience, criticizing the draft guidance's *in vitro* approach."

75. The FDA largely rejected the requests in the February 2014 Citizen Petition, explaining in its November 20, 2014 response to Allergan that the *in vitro*-only option in its June

2013 draft guidance was consistent with "the Agency's authority to make bioequivalence determinations on a case-by-case basis using *in vivo*, *in vitro*, or both types of data," which enabled the FDA "to effectuate several long-standing policies that protect the public health" when approving ANDAs for generic drugs.

76. The FDA explained that with respect to "locally acting, non-systemically absorbed drug products" like Restasis, the *in vivo* studies urged by Allergan's citizen petition were "usually of limited utility." It noted that, while its 2013 draft guidance for Restasis ANDAs had recommended using either *in vivo* or *in vitro* studies, the "modest efficacy demonstrated by Restasis" meant that an *in vivo* bioequivalence study "may not be feasible or reliable." The November 20, 2014 letter explicitly denied Allergan's request that Restasis ANDAs based on *in vitro* bioequivalence studies be rejected. FDA informed Allergan that the FDA concluded that "an *in vitro* study is likely more sensitive, accurate, and reproducible than a comparative clinical endpoint study to establish bioequivalence" for generic Restasis.

77. The FDA's rejection of the February 2014 Citizen Petition did not dissuade Allergan from its efforts to further delay generic competition for Restasis by abusing the citizen petition process. Allergan submitted a second citizen petition on December 23, 2014 (the "December 2014 Citizen Petition"), which largely repeated the arguments in the February 2014 Citizen Petition. Allergan supplemented the December 2014 Citizen Petition four times, including an August 16, 2015 supplement in which Allergan requested (among other things) that the FDA convene a committee of outside experts to evaluate the use of *in vitro* methods for generic Restasis, and that the FDA refuse to receive, review or approve any Restasis ANDAs until that outside evaluation was complete.

78. The FDA rejected the December 2014 Citizen Petition and its many supplements. In its February 10, 2016 response, FDA explained that the December 2014 Citizen Petition

"repeat[ed] many of the assertions that were at the center of Allergan's previous petition," and declined to repeat the agency's detailed answers from its November 20, 2014 response to the February 2014 Citizen Petition.[7] The February 10, 2016 letter again expressed doubts about the *in vivo* studies that Allergan asked the FDA to require for any Restasis ANDA. It concluded that the claims in the December 2014 Citizen Petition "lack legal support" and "rest on flawed logic." Despite the FDA's misgivings about the lack of sound, substantive bases for Allergan's citizen petitions, it was nonetheless obligated to specifically respond to each of Allergan's requests, and informed Allergan in its February 10, 2016 letter that it would "not approve or receive any ANDA referencing Restasis based on *in vitro* assays unless and until FDA responds specifically to the findings of Allergan's testing of nine experimental test emulsions" submitted with the December 2014 Citizen Petition. In other words, the FDA delayed the approval of any Restasis ANDA because of Allergan's serial citizen petition campaign. Allergan's tactic succeeded.

F. Allergan's Agreement with the Saint Regis Mohawk Tribe to Avoid PTAB Invalidation of the follow-on patents.

79. Allergan's latest effort to forestall competition in the market for cyclosporine stems from a series of *inter partes* review (IPR) requests. In June 2015, Apotex, which subsequently provided Allergan notice of its follow-on patent paragraph IV certifications on July 23, 2015, was the first ANDA applicant to petition the PTAB to initiate an IPR review of the follow-on patents. Allergan settled the Apotex IPR proceedings in December 2015, on undisclosed terms, just days before the PTAB was set to determine the likelihood that it would

[7] The FDA nominally granted two minor requests, but they did not change the FDA's practice. In the absence of Allergan's petitions, the FDA would have taken those requested actions anyway.

invalidate the follow-on patents.[8] By that time, however, other ANDA applicants, including Mylan and Teva, had also petitioned the PTAB for IPR proceedings on the follow-on patents. In December 2016, the PTAB resolved the same question that the Allergan settlement with Apotex mooted the year before: the PTAB concluded that there was a reasonable likelihood that each of the follow-on patents would be invalidated upon the PTAB's further review and instituted proceedings against all six of the follow-on patents.

80. In September 2017, Allergan entered into an agreement with the Tribe that purported to convey ownership of the follow-on patents to the Tribe with an exclusive license back to Allergan for "all FDA-approved uses in the United States" and a promise not to waive the Tribe's sovereign immunity with respect to any IPR or other administrative action in the PTO related to the patents. The agreement provided for a payment to the Tribe of $13.75 million from Allergan, plus potentially $15 million in annual royalties. On September 22, after the Tribe and Allergan agreed to this sham transfer of property rights, Allergan, using the Tribe as a conduit, petitioned the PTAB to dismiss the remaining pending IPRs for lack of jurisdiction based on tribal sovereign immunity. The sole purpose of this agreement was to eliminate the pending IPRs from the jurisdiction of the PTAB and avoid a decision on the merits, because Allergan was fully aware that the patents it was attempting to enforce were invalid and unenforceable.

81. No objectively reasonable litigant could expect these shenanigans before the PTAB to succeed. Multiple cases have rejected similar schemes to game the law, including in the context of sovereign tribes where the only interest the tribe had was in being paid for the

[8] Because the terms of Allergan's settlement with Apotex in December 2015 (that avoided for as much as a year any risk that any of the follow-on patents would be invalidated) were not made public, it is not possible to determine the extent to which that settlement may have violated *FTC v. Actavis*, 133 S. Ct. 2223 (2013), and thus constitute yet another component in Allergan's overall scheme.

cover of immunity. *See People ex rel. Owen v. Miami Nation Enters.*, 386 P.3d 357 (Cal. 2016). The trial court in the infringement case which Allergan recently lost agreed to join the Tribe as a co-plaintiff, but only as a hedge to ensure that any judgment it rendered would apply to the Tribe as well. The court explained that, despite its "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed," it would "adopt the safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings, where it is directly presented." *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-01455, ECF No. 522 at 4, 9 (E.D. Tex. Oct. 16, 2017).

82. Allergan has made no secret of its subjective bad faith in seeking to add the Tribe as a defendant in the IPRs. Allergan's chief executive, Brent Saunders, explicitly acknowledged that Allergan pursued the deal with the Tribe not to advance competition on the merits, but rather to avoid "double jeopardy." That is, Allergan sought to intentionally disrupt adjudicative proceedings in one of the two venues for the Restasis patent disputes (the PTAB), even though Allergan itself had initiated proceedings in the other (federal court) and could voluntarily dismiss that other action at any time.

83. The Tribe, for its part, entered the agreement for the money. The Tribe is not entering the pharmaceutical industry, and in fact, has publicly disclaimed any actual business interest in the pharmaceutical industry.[9] Licensing the follow-on patents back to Allergan was not a natural outgrowth of any ownership interest the Tribe had prior to September 2017, and,

[9] See Saint Regis Mohawk Tribe Office of Technology, Research and Patents, *Frequently Asked Questions About New Research and Technology (Patent) Business* at 1, https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf (last visited July 5, 2018) ("[T]he Tribe is not investing any money in this business. Its only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date.").

from the Tribe's comments, is not made pursuant to a natural future interest either. Nor was the Tribe acting in its sovereign capacity, e.g., regulating the sale or use of cyclosporine on a reservation, in entering its agreement with Allergan.

G. One or More ANDA Applicants Would Have Been Ready, Willing, and Able to Manufacture and Distribute Commercial Quantities of Generic Restasis in May 2014 Upon Expiration of Ding I.

84. Beginning in 2011, and continuing in 2012 and thereafter, numerous pharmaceutical manufacturers -- including some of the biggest pharmaceutical companies in the world -- submitted ANDAs seeking the FDA's approval to market generic Restasis. But for Allergan's misconduct as alleged herein, one or several of these ANDA filers would have received FDA approval and would have been in a position to supply the commercial quantities of generic Restasis necessary to supply the market as early as May 17, 2014, when the Ding I patent expired.

85. The long list of generic companies that to date have filed ANDAs seeking to market generic Restasis includes Watson, Teva, Mylan, Akorn, Apotex, Innopharma (Pfizer subsidiary), Famy Care, Twi Pharmaceuticals, and Deva Holding. But for Allergan's improper Orange Book listing, citizen petitions, and/or patent suits, some or all of these generic competitors would have been approved and on the market as early as May 17, 2014 -- over thirty months after the first ANDA seeking approval for generic Restasis was filed with the FDA -- and in any case well before today. As noted above, there is still no generic version of Restasis on the market.

86. The existence of multiple Orange Book-listed patents, multiple citizen petitions, ongoing patent litigation, and the cumulative effect of the foregoing can act as a disincentive for generics considering whether and when to submit and aggressively pursue approval of a

particular ANDA. The process of contesting even baseless (but complicated) legal or scientific assertions necessarily adds to the time and resources required for the generic approval process, both with respect to the ANDA applicants seeking generic approval and the FDA in reviewing those applications, all of whom must set priorities to allocate limited resources.

87. ANDA filers are less likely to aggressively pursue the filing or approval of ANDAs when faced with these added hurdles and complications, and the FDA has fewer resources available for legitimate scientific research when it is forced to respond to a series of extensive but baseless citizen petitions. Moreover, FDA has policies to prioritize or expedite review of ANDAs that otherwise have a clear path to market (as would have been the case for Restasis ANDAs as of May 2014 were it not for Allergan's serial sham patent litigation and citizen petitioning).

88. The Restasis ANDA filers that nonetheless sought to bring generic Restasis to market had no choice but to contend with the resulting hurdles. As Mylan's CEO Heather M. Bresch stated in Mylan's November 3, 2017 earnings call, "I think this is a great example of [Mylan] persevering through what I would call [Allergan's] pretty desperate legal maneuvers to try to maintain a monopoly that should have been gone a couple of years ago, and our ability continue to fight not only in the courts, but with the science and have a clear pathway to approvals."

89. Had scientists, regulatory professionals, and lawyers at Mylan, other generic manufacturers, and the FDA not been tied up by Allergan's "desperate legal maneuvers," and had they not been forced for years to "continue to fight" Allergan's anticompetitive conduct, they would have remained focused solely on ensuring that safe and effective generic version(s) of Restasis were approved "years ago" at, or shortly after, the expiration of the '979 patent on

May 17, 2014. This delay in competition is exactly what Allergan intended to cause, and did in fact cause, through its unlawful scheme.

VI. INTERSTATE COMMERCE

90. The drugs at issue in this case are sold in interstate commerce. Allergan's unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VII. MARKET POWER AND DEFINITION

91. There is direct evidence sufficient to establish Allergan's monopoly power without defining a relevant market and calculating market shares, including the extremely high profit margins Allergan earned on sales of Restasis and the money and effort it expended to delay generic competition, neither of which would have occurred in a competitive market. To the extent that market definition and market share are deemed to be required, the relevant product market is Restasis and its AB-rated generic equivalents, and the relevant geographic market is the United States.

92. At all relevant times, Allergan's share of the relevant market was, and remains, 100%.

93. At all relevant times, Allergan had monopoly power in the market for Restasis and its AB-rated generic equivalents because it had the power to maintain the price of Restasis at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Restasis.

94. Allergan has enjoyed monopoly power since 2003, when it launched Restasis upon FDA approval of its NDA. When it received FDA approval in December 2002, Allergan represented that Restasis was "the first and only therapy for patients with keratoconjunctivitis sicca (chronic dry eye disease-CDED) whose tear production is presumed to be suppressed due

to ocular inflammation." In its numerous filings with the FDA, Allergan has similarly represented the uniqueness of Restasis: "RESTASIS is a pathbreaking product that was developed to treat the widespread and sometimes debilitating problem of dry eye disease. Before RESTASIS, dry eye disease was a largely unmet medical need. After years of FDA-required clinical trials, Allergan was able to produce a precisely formulated drug that has significant efficacy in treating dry eye disease." Allergan, Inc., Citizen Petition, Feb. 28, 2014, at 13.

95. Manufacturers attempt to differentiate brand name drugs like Restasis based on features and benefits (including safety and efficacy), and not price.

96. Other products used to treat dry eye disease are not economic substitutes for cyclosporine. Artificial tears offer only ephemeral relief and do nothing to address the underlying causes of dry eye. Corticosteroids can address the inflammation associated with dry eye, but have unwanted side effects, as do devices like "punctal plugs," which block the tear ducts and help the eye retain naturally produced tears longer. Patients treated with cyclosporine would not switch to these products in response to a small but significant non-transitory increase in the price of cyclosporine in sufficient numbers to make such a price increase by a hypothetical monopolist unprofitable. Shire US, Inc.'s introduction last year of an alternative branded dry eye treatment, Xiidra, has not resulted in lower Restasis prices or lower sales, thus confirming Allergan's continued market power over the relevant cyclosporine market.

97. Allergan's ability to double the price of Restasis over the past decade without loss of significant sales further demonstrates the lack of substitutability between Restasis and other drug products.[10] Restasis does not exhibit significant, positive cross-price elasticity of demand

[10] See David Crow, *Allergan Deal with Mohawk Tribe Casts Patent Shadow*, FIN. TIMES, Sept. 27, 2017 ("The average wholesale price of a 30-dose pack of Restasis has more than doubled from $117 in 2008 to almost $280 today").

with any other medication. Other treatments may exist, but none exhibit cross-price elasticity with and therefore do not constrain the price of Restasis. The existence of these non-cyclosporine products that may be used to treat similar indications as Restasis did not constrain Allergan's ability to raise or maintain Restasis prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market as Restasis. Therapeutic alternatives are not necessarily economic substitutes.

98. Functional similarities between Restasis and other medications, other than AB-rated generic Restasis, are not sufficient to make these other molecules part of the relevant market with Restasis. To be an economic substitute for antitrust purposes, a functionally similar product must also exert sufficient pressure on the prices and sales of another product, so that the price of that product cannot be maintained above levels that would otherwise be maintained in a competitive market. No other medication (except AB-rated generic Restasis, which is not yet on the market) will take away sufficient sales of Restasis to prevent Allergan from raising or maintaining the price of Restasis above levels that would otherwise prevail in a competitive market.

99. Restasis is also not reasonably interchangeable with any products other than AB-rated generic Restasis because Restasis has significantly differentiating attributes making it a unique drug product. The FDA does not consider Restasis interchangeable with any other medication. Nor does Allergan. For example, Restasis is a topical ophthalmic formulation, and as Allergan has explained, "[u]nlike other drug delivery routes, a topical ophthalmic formulation usually delivers drug to the ocular tissues in relatively short timeframe of a few minutes." Allergan, Inc., Comment re Docket No. FDA-2007-D-0369—June 2013 Draft Bioequivalence Guidance for Cyclosporine Ophthalmic Emulsion, 0.05%, Aug. 17, 2013, at 13.

100. Allergan needed to control only Restasis and its AB-rated generic equivalents, and no other products, to maintain the price of Restasis profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Restasis would render Allergan unable to maintain its monopoly prices of Restasis without losing substantial sales.

101. Allergan also sold Restasis at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

102. Allergan has, and has exercised, the power to exclude competition.

103. Allergan, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market of cyclosporine ophthalmic emulsion due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and the high costs of entry and expansion.

VIII. MARKET EFFECTS OF ALLERGAN'S SCHEME

104. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic cyclosporine ophthalmic emulsion products on or shortly after May 17, 2014, when the exclusivities associated with Ding I and related patents expired. Instead, Allergan willfully and unlawfully maintained its monopoly power in the market for cyclosporine ophthalmic emulsion through a scheme to exclude competition. The scheme forestalled generic competition and anticompetitively maintained supracompetitive prices for Restasis. Allergan implemented its scheme by fraudulently obtaining the follow-on patents, wrongfully listing these knowingly invalid patents in the Orange Book, prosecuting sham patent infringement lawsuits against the generic manufacturers, submitting sham citizen petitions to the FDA and otherwise abusing the Hatch-Waxman framework, and entering into an

anticompetitive agreement with the Tribe in a blatant attempt to insulate the follow-on patents from invalidation in the PTAB IPR proceedings. These acts, individually and in combination, were anticompetitive.

105. If Allergan had not defrauded the PTO, (i) the follow-on patents would never have been issued, (ii) Allergan could never have used those follow-on patents as a vehicle to bring sham suits, predicated on knowingly invalid patents, against would-be makers of generic cyclosporine ophthalmic emulsion products, the filing of which automatically stayed any FDA final approvals of all would-be generic alternatives, and (iii) AB-rated generic Restasis manufacturers would have been able to launch generic cyclosporine ophthalmic emulsion products on or shortly after May 17, 2014.

106. Allergan's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Restasis from generic competition. Allergan's actions allowed it to maintain a monopoly and exclude competition in the market for ophthalmic cyclosporine ophthalmic emulsion, i.e., Restasis and its AB-rated generic equivalents.

107. Allergan's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Restasis without generic competition. But for the illegal conduct of Allergan, one or more of the generic manufactures that filed an ANDA to sell generic Restasis would have begun marketing generic versions of Restasis on or shortly after May 17, 2014.

108. The generic manufacturers seeking to sell generic Restasis have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand. One or more of these generic manufacturers would have been

ready, willing, and able to launch a generic version of Restasis as early as May 17, 2014 were it not for Allergan's unlawful acts.

109. Allergan's anticompetitive conduct delayed the introduction into the U.S. marketplace of any generic version of Restasis, has caused and will cause, Plaintiffs to pay more than they would have paid for cyclosporine ophthalmic emulsion in the absence of Allergan's unlawful conduct.

110. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Allergan, Plaintiffs and/or their assignors would have paid less for cyclosporine ophthalmic emulsion by substituting purchases of less expensive AB-rated generic Restasis for their purchases of more-expensive branded Restasis.

111. Thus, Allergan's unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT AND CONTINUING INJURY TO PLAINTIFFS

112. During the relevant period, Plaintiffs and/or their assignors purchased substantial amounts of Restasis directly from Allergan. As a result of Allergan's unlawful anticompetitive conduct, Plaintiffs and their assignors were compelled to pay, did pay, and continue to pay, artificially inflated prices for their cyclosporine ophthalmic emulsion requirements. Those prices were and are substantially greater than the prices that Plaintiffs and their assignors would have paid absent Allergan's illegal conduct.

113. As a consequence, Plaintiffs and their assignors have incurred substantial injury to their business and property in the form of overcharges.

114. Allergan's conduct threatens continuing loss and injury to Plaintiffs absent intervention and a grant of injunctive relief by this Court. Plaintiffs' injuries are ongoing. As a result of Allergan's scheme, there is no AB-rated generic version of Restasis available on the

market today. Even if a generic version of Restasis were launched tomorrow, it would take a significant period of time before competitive conditions in the relevant market became equivalent to the conditions that would have existed if generic Restasis had become available in 2014. The competitive effects of generic entry do not occur instantaneously. Thus, Plaintiffs are continuing to pay overcharges on their purchases of branded Restasis today and will continue to pay such overcharges for the foreseeable future.

115. In addition to the continuing harm suffered by Plaintiffs resulting from Allergan's anticompetitive conduct relating to Restasis, there is a substantial risk of future antitrust violations by Allergan relating to other drugs. Allergan and its affiliates are serial antitrust violators. Several drugs featured on Allergan's web site have been the subject of prior or pending antitrust cases, including Namenda, *see New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015); *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 2693713 (S.D.N.Y. June 21, 2017); Loestrin, see *In re Loestrin 24 FE Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016); and Asacol, see *In re Asacol Antitrust Litig.*, 2017 WL 5196381 (D. Mass. Nov. 9, 2017). Allergan has also been sued for antitrust violations involving other prescription ophthalmic medications. See *Hartig Drug Co. v. Senju Pharm. Co., Ltd.*, 836 F.3d 261 (3d Cir. 2016). This Court has the authority to enjoin Allergan from engaging in future antitrust violations.

X. CLAIM FOR RELIEF

VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION BY MEANS OF AN OVERARCHING SCHEME

116. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 115 above.

117. From 1995 until the present (and with continuing effects hereafter), Allergan had and continues to have monopoly power in the market for Restasis and its AB-rated equivalents (ophthalmic cyclosporine emulsion). During the relevant time period, no other manufacturer sold a competing version of any ophthalmic cyclosporine emulsion product in the United States.

118. Allergan willfully and unlawfully maintained its monopoly power in the Restasis market from May 17, 2014 through at least the present day by engaging in an anticompetitive scheme to keep generic equivalents off the market -- not as a result of providing a superior product, business acumen, or historical accident.

119. Allergan knowingly and intentionally engaged in an anticompetitive scheme in order to maintain its monopoly power, the components of which either standing alone or in combination (in whole or part) were designed to block and delay, and in fact have blocked and delayed, the entry of AB-rated generic versions of Restasis. This scheme included:

- Prosecuting serial baseless patent applications and ultimately obtaining the follow-on patents by fraud by misleading the PTO and failing to exercise the duty of disclosure, candor, and good faith;
- Improperly listing the follow-on patents in the Orange Book;
- Engaging in multiple sham litigations;
- Submitting serial sham citizen petitions; and
- Abusing the Patent Trial and Appeal Board's *inter partes* review process through sham transfer of the follow-on patents to the Saint Regis Mohawk Tribe.

120. By means of this scheme, Allergan intentionally and wrongfully maintained monopoly power with respect to Restasis in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs have paid and continue to pay artificially inflated prices for their cyclosporine ophthalmic emulsion requirements.

121. Among other unlawful conduct, Allergan knowingly and intentionally committed Walker Process fraud to induce the PTO to grant the follow-on patents. Specifically, Allergan -- after repeated denials of prior substantially similar serial applications over more than a 10-year period -- submitted false sworn declarations in 2013, that Allergan characterized as presenting new data that showed surprising results not anticipated by prior art (i.e., Ding I), when in fact the data presented was years old and well known to anyone skilled in the art. Had Allergan made clear to the PTO examiner that the statements and data in the 2013 declarations were lifted from prior art known to Allergan for over 10 years, as Allergan's duty of disclosure, candor, and good faith required, the PTO examiner would have rejected all of the 2013 applications for the same reasons it had repeatedly denied every prior application: that the claims presented were all obvious in light of the prior art. Allergan's misstatements were material, fraudulent, and made knowingly and with the intent to deceive, and in fact induced the PTO to issue the follow-on patents.

122. Allergan's misrepresentations of fact to the PTO were made by and through its patent attorneys and scientists who submitted declarations in support of patentability (including Laura L. Wine, Dr. Rhett M. Schiffman, and Dr. Mayasa Attar)[11] and included:

- Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "surprisingly, the claimed formulation demonstrated a 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Allergan's Phase 3 trials compares to the relative efficacy for the . . . formulation discussed in Example 1E of Ding, tested in Phase 2 trials. This was clearly a very surprising and unexpected result."[12]

[11] *See Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2017 WL 4803941, at *38 (E.D. Tex. 2017)

[12] *Id.* at *11.

- Statements by Allergan's patent counsel that Dr. Schiffman's declaration showed "the claimed formulations also demonstrated a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the formulation tested in Phase 2 and disclosed in Ding. This was clearly a very surprising and unexpected result."[13]

- Figures 1-4 in Dr. Schiffman's declaration that reported figures from the Sall paper but omitted all error bars and p-values. In truth, as the Court later found, none of the pair-wise comparisons between the two cyclosporine formulations for corneal staining and Schirmer scores in the Phase 2 study or the pooled Phase 3 studies demonstrated statistical significance at any time point, and many of the p-values for the pair-wise comparisons were very high. The actual statistical analyses showed that any observed difference in raw numbers between the cyclosporine formulations was likely the result of random chance.

- Dr. Schiffman's failure to disclose to the PTO that he was comparing different Schirmer tear test scores -- one without anesthesia in Phase 2 and one with anesthesia in Phase 3 -- in order to purportedly show a difference in efficacy. As the Court later found, only the Schirmer tear test results with anesthesia in Phase 3 significantly favored the 0.05% cyclosporine formulation. "It was therefore only by comparing the results of two different types of tests that Dr. Schiffman was able to produce a significantly distorted picture suggesting that the [Phase 3 formulation' was much more effective than the [Phase 2 formulation]. This was both statistically and clinically improper.

- Dr. Schiffman's failure to disclose to the PTO that the method he "used in his declaration to calculate the differences in efficacy between the 0.05% and 0.1% cyclosporin formulations exaggerated the differences in the raw values between the two."[14]

- Misleading calculations in Dr. Schiffman's table including:

    a. Dr. Schiffman's use of ratios of the degree of improvement, which tends to overstate the difference between the results;

    b. Dr. Schiffman's failure to disclose that the Phase 2 study was quite small, and that the difference in the raw numbers between formulations were not statistically significant; and

[13] *Id.*

[14] *Id.*at *38.

c. Dr. Schiffman's inclusion of data only from favorable comparisons between the two formulations. He omitted categories where the Ding I formulation did better than the follow-on formulation.

- Dr. Schiffman's failure to tell the PTO that the data provided was taken from the Sall paper published more than a dozen years earlier (and three years before the priority date for the Restasis patents). Even if the results presented were surprising (they were not), they were publicly known before the date of invention and cannot be the basis for a claim that it was "unexpected" as of the Restasis patent's priority date.

123. These representations were material. The examiner had repeatedly rejected the applications as obvious before Allergan's misleading statements and omissions. The examiner had also earlier rebuffed Allergan's purported secondary considerations of non-obviousness (including commercial success and unmet need). The PTAB's later decision supports the materiality of these misrepresentations and omissions.

124. Allergan made these statements with intent to deceive the PTO. The misleading statements were made intentionally, not accidentally. Allergan was motivated to obtain a longer period of patent protection, given the large sales of Restasis and the importance of the product to the company. The misleading statements were made only after the examiner rejected the patent application, not at the time of the initial filing, and were made in order to overcome the rejection and support patentability. There is no innocent explanation for presenting the information as it was presented in the misleading declaration and accompanying submissions; the only reasonable inference is that Allergan intended to deceive the PTO.

125. The PTO reasonably relied on Allergan's false and misleading statements in issuing the follow-on patents. The examiner stated that the Schiffman declaration was sufficient to overcome his earlier rejection based on Ding I because the "[e]xaminer is persuaded that, unexpectedly, the claimed formulation . . . demonstrated an 8-fold increase in relative efficacy for the Schirmer Tear Test score in the first study of Phase 3 trials compared to relative efficacy .

. . for the formulation disclosed" in Ding I. The Examiner also explained that the declarations "illustrate that the claimed formulations . . . also demonstrate a 4-fold improvement in the relative efficacy for the Schirmer Tear Test score for the second study of Phase 3 and a 4-fold increase in relative efficacy for decrease in corneal staining score in both of the Phase 3 studies compared to the . . . . formulation tested in Phase 2 and disclosed in Ding."[15]

126. After fraudulently obtaining its follow-on patents, Allergan enforced its patents against would-be generic competitors by listing them in the Orange Book and filing lawsuits alleging that they were infringed, thereby triggering 30-month stays of FDA approval and allowing Allergan to maintain its monopoly in the relevant market.

127. Allergan knew when it listed the follow-on patents in the Orange Book that these patents were fraudulently procured and/or were otherwise invalid as obvious in light of prior art, namely Ding I and the related patents, and that therefore the follow-on patents should not have been listed in the Orange Book. Allergan knew that listing the follow-on patents in the Orange Book would force ANDA applicants to file paragraph IV certifications that would thereby provide Allergan the opportunity to file patent infringement suits against those ANDA applicants that, regardless of the baselessness of such suit, could trigger an automatic stay of any FDA final approval of any new paragraph IV-certified ANDA applicant's generic Restasis product for a period of up to 30 months.

128. Allergan knowingly and intentionally engaged in multiple sham litigations against manufacturers of AB-rated generic equivalents of Restasis. Allergan intentionally and deceptively alleged that the generic manufacturers' products infringed its follow-on patents, knowing when those suits were filed that such patents were wrongfully obtained though fraud on

[15] *Id.*at *11.

the PTO and were otherwise invalid as obvious in light of the prior art, namely Ding I and the related patents. Allergan also knew, at the time those multiple sham suits were filed, that it had no realistic likelihood of success; that is, that there was no realistic likelihood that a court would enforce the fraudulently-obtained and otherwise invalid follow-on patents against a generic company. Allergan knew, therefore, that no reasonable pharmaceutical manufacturer would have believed it had a reasonable chance of succeeding on the merits of these infringement lawsuits. Allergan filed this sham lawsuit for the purposes of using a governmental process as an anticompetitive weapon to keep generics off the market and wrongfully maintain its monopoly power over Restasis, regardless of any actual merit to its infringement claims.

129. Allergan knowingly and intentionally submitted multiple and serial sham citizen and other petitions to the FDA with the purpose and intent to delay the FDA's approval of any of the pending generic ANDA applications, regardless of any objective merit to any part or parts of any petition. Each of the citizen petitions alone and in combination were baseless and filed only to delay generic Restasis.

130. Allergan knowingly and intentionally entered into an agreement in which it paid the Tribe for accepting a transfer of the follow-on patents to the Tribe -- a sovereign tribe that does not manufacture or distribute pharmaceutical products of any kind and is better known for its operation of casinos on tribal lands located in New York -- in an attempt to evade a decision on the merits invaliding the patents and ending its Restasis monopoly. This agreement reflects Allergan's certainty that the follow-on patents would not survive scrutiny. The agreement between Allergan and the Tribe was both an independently unlawful conspiracy in restraint of trade under section 1 of the Sherman Act and an element in Allergan's overall monopolization scheme.

131. There is no valid procompetitive business justification for Allergan's anticompetitive conduct in whole or in part.

132. But for Allergan's scheme, there would have been no impediment to generic versions of Restasis entering the market from approximately May 17, 2014 onwards. But for the scheme, generic Restasis would have been available for purchase in the United States on or shortly after May 17, 2014.

133. Plaintiffs have been injured in their business or property by Allergan's antitrust violations and are continuing to suffer such injury. Plaintiffs' actual and threatened injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Allergan's conduct unlawful.

XI. DEMAND FOR JUDGMENT

134. WHEREFORE, Plaintiffs pray for judgment against Defendant and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Section 2 of the Sherman Act;

B. Permanent injunctive relief (i) enjoining Defendant from continuing their illegal conduct; (ii) enjoining Defendant from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of other generic drugs; and (iii) requiring Defendant to take affirmative steps to dissipate the continuing effects of their prior unlawful conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XII. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: August 6, 2018

Respectfully submitted,

/s/ Andrew M. Erdlen
Andrew M. Erdlen
Barry L. Refsin*
Maureen S. Lawrence*
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
One Logan Square, 27th Floor
Philadelphia, PA 19103
(215) 568-6200
aerdlen@hangley.com
brefsin@hangley.com
mlawrence@hangley.com

Monica L. Kiley*
Eric L. Bloom*
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
2805 Old Post Road, Suite 100
Harrisburg, PA 17110-3676
(717) 364-1030
mkiley@hangley.com
ebloom@hangley.com

* *Pro hac vice* motion forthcoming.